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TRANSMITTAL OF APPEAL BRIEF

Docket No.
HO-P02191US0

In re Application of: Per Andersson et al.

Application No.
09/674,457-Conf. #8539Filing Date
May 7, 1999Examiner
D. K. HandyGroup Art Unit
1743

Invention: MICROFLUIDIC DEVICE

TO THE COMMISSIONER OF PATENTS:Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal
filed: December 20, 2005The fee for filing this Appeal Brief is \$ 500.00☒ Large Entity ☐ Small Entity☐ A petition for extension of time is also enclosed.

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Docket No.: HO-P02191US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Per Andersson et al.

Application No.: 09/674,457

Confirmation No.: 8539

Filed: May 7, 1999

Art Unit: 1743

For: MICROFLUIDIC DEVICE

Examiner: D. K. Handy

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed more than two months after the Notice of Appeal filed in this case on October 20, 2005, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

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This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is the assignee, GYROS AB.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Claims 1-19 were originally filed on January 5, 2001 in this case, which is the National Phase Application of PCT Application No. IB99/00907 filed May 7, 1999 claiming priority to United Kingdom patent application 9809943.5, filed on May 8, 1998.

B. Current Status of Claims

Claims 20 - 41 were added in a preliminary amendment dated July 25, 2002.

Following an Office Action mailed July 7, 2003, a response was filed on November 7, 2003 canceling claims 1 - 19, 21, 32, 34 - 35, and 37 - 40; amending claims 20 and 27 - 31; and adding claims 42 - 47.

A final Office Action was mailed on February 3, 2004 rejecting the outstanding claims 20 - 31, 33, 36 and 41 - 47. An RCE was filed August 3, 2004 canceling claims 29 and 30.

An Office Action mailed September 24, 2004, rejected the outstanding claims 20, 22 - 28, 31, 33, 36 and 41 - 47. A response was filed on February 22, 2005 canceling claims 20, 22 - 28, 31, 33, 36 and 41 - 42; amending claim 43; and adding claims 48 - 49.

A final Office Action was mailed on May 23, 2005 rejecting the outstanding claims 43 - 49.

C. Claims On Appeal

The claims on appeal are claims 43 – 49.

IV. STATUS OF AMENDMENTS

Applicant filed a response with amendments on February 22, 2005. The Examiner's final Office Action mailed May 23, 2005 acknowledged entry of these amendments. No subsequent amendments are outstanding.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is a method of use for a co-disclosed circular microfluidic device (Figures 4-8). Specifically, it is a method of controlling the flow of a liquid sample in the device by way of intermittent regions of relatively hydrophobic and hydrophilic surfaces. (Page 3, lines 14-22; Page 6, lines 12-14; Figure 7: 14 and 15; Figure 8: Hydrophobic breaks A, B, C, and D). The fluid is placed into the device at an inlet. Generally, the fluid is a liquid which flows via capillary and/or centrifugal forces to a hydrophobic section within a predetermined hydrophilic pathway of the circular microfluidic apparatus. (Page 6, lines 12-16). The hydrophobic section prevents the aqueous solution from flowing further along the pathway. *Id.* Increased centrifugal force drives the aqueous solution through the hydrophobic section of the pathway allowing the fluid to continue to a distal portion of the microfluidic device. *Id.* Thus, these hydrophobic stop sections function as fluid valves to control the flow of samples between different parts of the hydrophilic pathway of the device.

VI. GROUNDS OF OBJECTION TO BE REVIEWED ON APPEAL

Whether claims 43 – 49 were properly rejected under 35 U.S.C. § 103(a) as obvious over Kellogg, et al. (US6,143,248) in view of Burns et al. (US6,379,929).

VII. ARGUMENT**A. Issues Under 35 U.S.C. § 103(a) Claim Rejections**

Claims 43 – 49 are rejected under 35 U.S.C. § 103(a) over Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929).

1. REFERENCES MUST HAVE ALL ELEMENTS OF THE CLAIMED INVENTION

To establish *prima facie* obviousness, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974); *CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (“The examiner concluded that no combination of the prior art, even if supported by a motivation to combine, would disclose all the limitations of the claims. In other words, the examiner detected, in light of all limitations of the claims, no obviousness.”). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988).

The current process claims all incorporate the element “wherein the inlet is capable of handling less than about 500 nl.”

The Examiner has based his Final Rejection on a misunderstanding of the law. Specifically, the Examiner has stated as a matter of law that a limitation using the phrase *capable [of]* “carries no patentable weight”. (Citing *In re Hutchison*, 69 U.S.P.Q. 138 (CCPA 1946)); See Examiner’s Final Rejection dated 05/23/05, pg 4, lines 1-5. The language discounted in *In re Hutchison* used “adapted for” while a subsequent element using “capable of” was unobjectionable. *Id.* at 141. Thus the Examiner’s is wrong on the specifics. More broadly, as explained in *Kropa v. Robie*, 88 U.S.P.Q. (BNA) 478 (CCPA 1951), the reason for the court in *In re Hutchison* discounting the “adapted for” term is because “adapted for” was part of an introductory preamble and not an actual claim element. *Id.* at 480-481, Appendix n19 (“[T]he preamble merely stated a purpose or intended use of that subject matter.”); See also MPEP 2173.05(g) (Functional Limitations); MPEP 2111.02 (Effect of Preamble).

The Examiner then addresses the “wherein the inlet is capable of handling less than about 500 nl” element anyway. See Examiner’s Final Rejection dated 05/23/05, section 4, pgs 3-4. The Examiner acknowledges that Kellogg et al. does not disclose use of nanoliter volumes. *Id.* pg 3, lines 2-3. The Examiner and his Supervisor “did not *feel* that this excluded Kellogg from manipulating” volumes within the claim limit. (emphasis added). *Id.* at 3. Later, the Examiner asserts, “Examiner *believes* that an entry port ‘having a volumetric

capacity of 1 to about 100 (or 150) microliters is indeed capable of handling less than that amount.” *Id.* pg 4, lines 5-7 (emphasis added). Based on feelings and beliefs, the Examiner has demanded that Applicant prove Kellogg et al. cannot accommodate liquid sample volumes in the 500 nl or less range. *Id.* pg 3, lines 10-19. This rejection seems to be based on inherency of the claimed volume limitation relative to the Kellogg et al. reference.

“The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103.” MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof). Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The Examiner has not provided “a basis in fact and/or technical reasoning” to determine that Kellogg et al. **necessarily** allows for use of nanoliter sample volumes. *See* Examiner’s Final Rejection dated 05/23/05, section 4, pgs 3-4. Instead the Examiner has required Applicant to *disprove* the inherent existence of a claim limitation in Kellogg et al. *Id.* The Examiner has not made a *prima facie* case that “wherein the inlet is capable of handling less than about 500 nl” is necessarily present in Kellogg et al. Thus, the obviousness rejection relying on Kellogg et al. should be overruled.

2. NO MOTIVATION TO COMBINE

When an obviousness determination is based on multiple prior art references, there must be a showing of some teaching, suggestion or reason to combine the references. *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340 (Fed. Cir. 2000). “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found

either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” MPEP § 2143.01.

The Examiner rejected the appealed claims because the Examiner “believes that one of skill in the art would recognize”:

1) The use of hydrophobic stops disclosed by Burns et al. would allow multiple stops per fluid pathway. *See* Examiner’s Office Action Dated 9/24/04, pg 3.

2) The stopping mechanism of Burns et al. would variously “save energy” or require “less force” relative to the stopping mechanism of Kellogg et al. *Id.* at pg 3, 6, 7.

3) Combining the hydrophobic stops from Burns et al. with the microfluidic device in Kellogg et al. would make manufacturing of the derived microfluidic device “easier” because “less area on the disc would be required” to form joints between reservoirs and channels. *Id.* at pg 7.

The Examiner points to no teaching or suggestion in the cited references to support these. *See* Examiner’s Office Action Dated 9/24/04, pg 3, 6-7; Appendix B. Instead, the Examiner appears to rely upon “the knowledge generally available to one of ordinary skill in the art.” MPEP § 2143.01.

The level of skill in the art alone cannot be bootstrapped to eliminate the need for a motivation to combine. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). The analysis and validation of a motivation to combine must be specific, thorough and searching. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002); Cf. *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1338 (Fed. Cir. 2005) (Comparing *In re Lee* and finding the evidence “supplied detailed analysis of ... the reasons that one of ordinary skill would possess knowledge and motivation to combine....”). The “factual question of motivation is material to patentability” and can not be based on “subjective belief and unknown authority.” *In re Lee*, 277 F.3d at 1344.

The Examiner uses sparse semi-conclusory statements discussing the alleged motivations to combine. *See* Examiner’s Office Action Dated 9/24/04, pg 3, 6-7; Appendix

B. These statements are comparable to the ones the *In re Lee* court rejected. *Id.* at 1343 (Conclusory statement that ‘another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial’ did not adequately address the issue of motivation to combine.). The Examiner’s statements are also based on “subjective belief and unknown authority” rather than a reasoned and substantiated explanation of why one of skill in the art would be motivated to combine the cited references. As such, these Examiner statements are insufficient to establish a *prima facie* case.

3. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

The Examiner’s reliance upon Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929) would change the principle of operation in Kellogg et al. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP 2143.01 at IV (citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Kellogg et al. teaches valves that are based on a change in a cross-sectional dimension of a microchannel such that capillary forces will prevent liquid to pass the change absent added centrifugal force. The change is typically abrupt. *See* Kellogg et al. at Column 14, lines 5-21 and lines 40-45; Column 15, lines 13-37; Column 16, lines 31-54; Column 18, line 18 through Column 20, line 24; etc. In regard to hydrophobicity and hydrophilicity of the materials in Kellogg et al., the functional point made in Kellogg et al. is that of wetting and non-wetting conditions, which depends on the material of the microfluidic device and the nature of the fluid. *Id.* at Column 14, lines 5-21 and lines 40-45; Column 15, lines 13-37. Wetting or non-wetting combinations result in capillary “valving” at junctions of smaller to larger dimensioned elements or larger to smaller dimensioned elements, respectively. *Id.*

The invention disclosed by Kellogg et al. is centered on new microfluidic devices designed to control fluid movement using capillary valving mechanisms. *Id.* at Column 1, lines 15-22. These newly designed capillary valves overcome prior art problems with fluid movement control in microfluidic devices. *Id.* at Column 3, lines 1-36. Replacing the capillary valves in Kellogg et al. with hydrophobic patch valving within a fluid pathway

would fundamentally alter the operative principle of this key point of novelty for the Kellogg et al. invention. The Examiner relies upon such a combination to establish his *prima facie* case of obviousness. See Examiner's Office Action Dated 9/24/04, pg 7, para. 1; Examiner's Office Action Dated 5/23/05, pg 2, section 2. Hence, the Examiner has failed to establish a *prima facie* case and the rejection should be overruled.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

IX. EVIDENCE

No evidence is submitted, hence no Appendix is included.

X. RELATED PROCEEDINGS

No related proceedings are referenced in II. above. No copies of decisions in related proceedings are not provided, hence no Appendix is included.

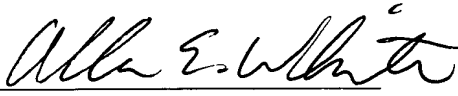
XI. CONCLUSION

Appellants have provided arguments that overcome the pending rejections. Appellants respectfully submit that the Action's conclusions that the claims should be rejected are unwarranted. It is therefore requested that the Board overturn the rejection of the Action. Appellants respectfully request that the Board recommend that this application proceed to allowance.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

Dated: December 20, 2005

Respectfully submitted,

By 

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/674,457

43. A method for controlling flow of a liquid in a microfluidic device comprising the steps of:

adding liquid to an inlet of a circular microfluidic device that is adapted for rotation about its axis, wherein said device comprises two substrates between which there are predetermined pathways for liquid flow, and wherein the inlet is capable of handling less than about 500nl of a liquid sample and the liquid flows down the hydrophilic pathway until the liquid reaches a hydrophobic section or valve in the pathway preventing the flow of liquid; and

applying sufficient energy to the liquid allowing it to pass the valve and continue to flow down the pathway.

44. The method of claim 43, wherein the liquid flows down the hydrophilic pathway to the valve by capillary action.

45. The method of claim 43, wherein the energy is centrifugal force created by rotating the device.

46. The method of claim 43, wherein the liquid has a surface tension $> 18 \text{ mNm}^{-1}$.

47. The method of claim 43, wherein the liquid is an aqueous solution or suspension having a surface tension $> 50 \text{ mNm}^{-1}$.

48. The method of claim 43, wherein the liquid sample comprises reagents.

49. The method of claim 43, wherein the liquid sample is between 1 to 10nl.

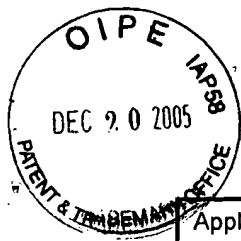
APPENDIX B

Motivation to Combine. Examiner's Office Action Dated 9/24/04, pg 3, 6-7.

It would have been obvious to combine the hydrophobic patches from Burns with the device of Kellogg. The use of hydrophobic regions within the channel would allow for multiple valves within a channel which could be used to stop fluid flow in several places instead of at just one interface. It would also lower the energy requirement for moving liquids further down the channels of the microfluidic network since Kellogg teaches a channel which is *entirely* hydrophobic and must use centripetal force for driving fluids through the entire channel.

The Examiner believes one of ordinary skill in the art would recognize that the stopping mechanism of Burns – the hydrophobic patch – would require less on an energy input to move the fluid move again that the stopping mechanism of Kellogg – which has an entire hydrophobic channel and a change in cross sectional area. Therefore, Kellogg could still use the centripetal force to drive fluids through the channels of their device – only now less force would be required. This is what the Examiner was referring to in the previous action when it was suggested that using Burns' hydrophobic patch would save energy.

The Examiner believes that one of ordinary skill in the art would recognize that the stopping feature of Burns would be an improvement on the stopping feature of Kellogg since it does not require the additional change in cross sectional area. This would require less centripetal energy to drive fluids through the device. It would also allow for easier fabrication of microfluidic networks on the disc since less area on the disc would be required when forming joints between reservoirs and inlet/outlet channels.



Application No. (if known): 09/674,457

Attorney Docket No.: HO-P02191US0

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